Mercodia

Mall-0618 v1.0

Certificate of Analysis

1. **Manufacturer**

Mercodia AB, Sylveniusgatan 8A, 754 50 Uppsala, SWEDEN

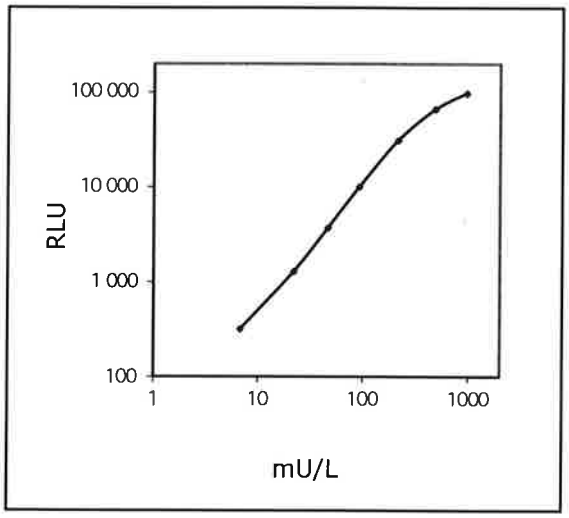
2. **Description**

Catalog no: 10-1371-01

Product: Insulin Northern Lights MBeads Assay

Lot no: Lj1371-058

Expiry date: 2027-01-31



Component	*Art no*	*Lot no*	*RLU*	*Exp. date*
Calibrator 0	20-7637	1371-034	90	2027-07-24
Calibrator 1, 6,73 mU/L	20-7638	1371-035	319	2027-08-07
Calibrator 2, 21,9 mU/L	20-7639	1371-035	1286	2027-08-07
Calibrator 3, 46,4 mU/L	20-7640	1371-035	3728	2027-08-07
Calibrator 4, 92,0 mU/L	20-7641	1371-035	10077	2027-08-07
Calibrator 5, 216 mU/L	20-7642	1371-035	31200	2027-08-07
Calibrator 6, 483 mU/L	20-7643	1371-035	66555	2027-08-07
Calibrator 7, 960 mU/L	20-7644	1371-035	98190	2027-08-07
MBeads Antibody	20-7648	1371-031	-	2027-08-22
Assay Buffer	20-7646	1371-033	-	2027-08-16
Enzyme Conjugate 44X	20-7647	1371-032	-	2027-08-15
Wash Buffer 21X	20-6746	32170	-	2028-03-12
Substrate Reagent A	20-7300	35950	-	2027-02-19
Substrate Reagent B	20-7301	35951	-	2027-02-19

Quality Control	*Art no*	*Lot no*	*Exp. date*	*Assigned range (mU/L)*	*Results (mU/L)*
Control	20-7645	1371-036	2027-08-07	55,9 – 130,5	90,3

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E-mail info@mercodia.com | **Website** www.mercodia.com

3. Quality control

Quality control has been performed for lot no Lj1371-058 according to standard operating procedures at Mercodia AB, and the product is released based on fulfillment of established acceptance criteria.

4. Calibration

Insulin Northern Lights MBeads Assay is calibrated against 1st International Reference Preparation 66/304.

5. Assay method

Test procedure used is according to current Direction for Use for the product and lot.

6. Intended use

Insulin Northern Lights MBeads Assay provides a method for the quantitative determination of insulin in perifusion samples.

7. Storage and handling

Recommended storage of kit is 2-8°C.
Storage of unused or diluted kit components is stated in the Direction for Use.

8. Hazardous information

Please refer to the Safety Data Sheet for hazard identification.

9. Quality standard documentation

The Mercodia Quality System fulfills the QSR and the requirements for the European CE mark, the Directive 98/79/CE on *in vitro* diagnostic medical devices. Mercodia is ISO 13485 certified, for compliance with the International Quality Management System for medical devices.

10. Names and signatures of certifying officers

Date of analysis:	Performed by:	Signature:
2024-10-14	Sara Pantasso, genom Jonas Hermansson	

Date of approval:	Approved by:	Signature:
2024-12-16	Jonas Hermansson	

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